DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Selenium, Vitamin E Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a previously approved supplemental new animal drug application (NADA) held by Schering-Plough Animal Health Corp. and to remove certain information no longer required in the regulations. The approval concerns use of selenium, vitamin E injection.

EFFECTIVE DATE: (*Insert date of publication in the* **Federal Register**.)

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., P.O. Box 1982, Union, NJ 07083–1982, provided information to support prior approval of supplemental NADA 30–315 for selenium, vitamin E injection. The supplement for use of 2 percent benzyl alcohol instead of 1:10,000 thimerosal had been approved by letter of August 10, 1981. FDA reviewed the information and concurred that the change in ingredient was approved. FDA also reviewed the information requirements of the animal drug regulations and determined that specification of ingredients other than active ingredients is not needed. Therefore, 21 CFR 522.2100 is amended to remove statement of ingredients other than active ingredients.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.2100 [Amended]

2. Section 522.2100 *Selenium, vitamin E injection* is amended in paragraph (a)(1) by removing ", 250 milligrams polyoxyethylated vegetable oil, and 2.0 percent benzyl alcohol, and water for injection"; in paragraph (b)(1) by removing ", 100 milligrams of polyoxyethylated vegetable oil,

1:10,000 thimerosal, and water for injection''; and in paragraphs (c)(1), (d)(1), and (e)(1) by removing '', 250 milligrams polysorbate 80, 2 percent benzyl alcohol, water for injection q.s''.

Dated: May 11, 1999

May 11, 1999

BJ Gudo 5-18-99

Margaret Ann Miller

Margaret Ann Miller
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Office of New Animal Drug Evaluation
Center for Veterinary Medicine

[FR Doc. 99–???? Filed ??–??–99; 8:45 am]

BILLING CODE 4160–01–F

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